K113126

510(k) Summary

JUL 17 2013

Date:	5 June 2013
Sponsor:	GERGEN'S ORTHODONTIC LAB INC 1745 West Deer Valley Rd, Suite 112 Phoenix, AZ 85027 Phone: 623-879-6066 Fax: 623-879-6166
Contact Person:	Chris Morrison, Lab Manager
Proposed Trade Name:	Acrylic Herbst Appliance
Common Name:	Anti-snoring appliance
Device Classification	Class II
Classification Name:	Device, Anti-Snoring
Regulation and Name:	872.5570, Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Device Product Code:	LRK
Device Description:	The Acrylic Herbst Appliance is comprised of upper and lower customized acrylic splints which are connected bilaterally via a telescoping Herbst mechanism for the treatment of mild to moderate sleep apnea. The device aims to improve the patient's air exchange thereby reduce snoring and apnea by increasing the pharyngeal space through anterior repositioning of the mandible.
Intended Use:	The Acrylic Herbst Appliance is intended for the reduction of night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults 18 years of age or older.
Materials:	Medical grade polymethylmethacrylate (acrylic splints) and stainless steel (Herbst mechanism)
Predicate Devices:	Allesee Orthodontic Appliances, Inc. (K070327) Specialty Appliances Works, Inc. (K083209) Dynaflex Inc. (K103076) Embassy Dental (K111009)
Performance Data:	Data regarding performance testing of the device material was provided in support of clearance. The data included general properties (water solubility and absorption) and physical properties (tensile and flexural strength, and elastic modulus). In addition, a risk analysis found no new safety concerns specific to the Gergen's Orthodontic Acrylic Herbst Appliance. Clinical testing of the subject device was not used in support of clearance.
Technological Characteristics:	The fundamental scientific technology of the Gergen's Orthodontic Acrylic Herbst Appliance is the same as previously cleared devices as shown below, i.e., each of the design features is common to one or more of the predicates.

System:	**Gergen's Orthodontic – Acrylic Herbst Appliance**	**Embassy Dental – Acrylic Herbst Appliance**	**Allesee Orthodontic – Removable Acrylic Herbst**	**Specialty Appliances – Acrylic Herbst Splint Appliance**	**Dynaflex Inc. – Adjustable Herbst Appliance**
Intended use/Indications for use::	The reduction of night time snoring and mild to moderate obstructive sleep apnea (OSA)	Same –	Same	Same	Same
Target population:	Adults	Same	Same	Same	Same
Prescription use:	Prescription only	Same	Same	Same	Same
Basic Design:	Upper and lower trays connected bilaterally by telescoping Herbst mechanisms	Same	Same	Same	Same
Function:	To increase the patient's the pharyngeal space and improve air exchange thereby reduce snoring and apnea by anterior repositioning of the mandible	Same	Same	Same	Same
Materials of manufacture:	Medical grade acrylic and stainless steel	Same	Same	Same	Same
Adjustability:	Yes, by prescribing dentist or physician	Same	Same	Same	Same
Method of manufacture:	Customized to the specifications of a single patient	Same	Same	Same	Same
Sterility:	Non-sterile	Same	Same	Same	Same

Conclusion:

In comparison to the predicate devices, the Acrylic Herbst Appliance has

- the same intended use (as described above),
- the same technological characteristics (as described above)

and so does not raise new questions of safety and effectiveness.

Therefore the Acrylic Herbst Appliance is as safe and as effective for its intended use, and performs as well as the predicate devices. The Acrylic Herbst Appliance can be found substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 17, 2013

Gergens Orthodontic Lab
C/O Karen E. Warden, Ph.D.
President
BackRoads Consulting, Incorporated
11825 Sate Route 40 Suite 101
DUNLAP IL 61525

Re: K113126
Trade/Device Name: Acrylic Herbst Appliance
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: June 5, 2013
Received: June 6, 2013

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

GERGENS ORTHODONTIC LAB INC

1745 West Deer Valley Rd
Suite 112
Phoenix, AZ 85027

510(k) Number: **K113126**

Device Name: **Acrylic Herbst Appliance**

Indications for Use:

The Acrylic Herbst Appliance is intended for the reduction of night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults 18 years of age or older.

Prescription Use [X] **AND/OR** Over-the-Counter Use [ ]
21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
Susan Runner DDS MA 2013.07.17
15:48:43 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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